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| 10/680,110 | 10/08/2003 | Stephen James Field | 0119/0027 | 4691 |

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| EXAMINER | |
|---|---|
| OSTRUP, CLINTON T | |
| **ART UNIT** | **PAPER NUMBER** |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

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| ***Office Action Summary*** | **Application No.**<br>10/680,110 | **Applicant(s)**<br>FIELD, STEPHEN JAMES | |
| | **Examiner**<br>CLINTON OSTRUP | **Art Unit**<br>3771 | |

***-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --***

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *10 November 2008*.
2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-18* is/are pending in the application.
  4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) *1-18* is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.
10)☒ The drawing(s) filed on *08 October 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.
  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  a)☒ All b)☐ Some * c)☐ None of:
    1.☒ Certified copies of the priority documents have been received.
    2.☐ Certified copies of the priority documents have been received in Application No. _____.
    3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
  * See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
  Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
  Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

1. This Office Action is in response to applicant's amendment filed November 10, 2008. As directed by the amendment, claims 2-11, 14-17 have been amended. Thus, claims 1-18 are pending in this application.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 2-11 and 14, and 16-17 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-11 are unclear confusing because it is unclear if they refer back to "the valve" of claim 1 or if they are describing a "Valve" that is different from the valve claimed in claim 1. For clarification purposes, the examiner respectfully suggest applicant claim "The valve" to positively identify claims 2-11 as referring back to "the valve" of claim 1.

Claims 14 and 16-17 are rejected for analogous reasons to those of claims 2-11, as set forth above.

### *Claim Rejections - 35 USC § 103*

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

> invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Russo (5,775,325) and further in view of Iund et al., (5,598,840).

Russo discloses a valve (figure 6) with a deformable member (formed by 24,25, 29 & 30) wherein the deformable member has a fluid passage (26) extending there through, and a normally-closed opening (28 is normally closed as shown in Figure 5 & 10) within the fluid passage arranged such that it can be opened by external pressure applied to said deformable member (when fingers press on 24 & 25 as shown in figure 7); and an external member (fingers) displaceable on said deformable member with respect to said deformable member between a first position (normally closed as shown in figure 5) at which said external member can be released and in which the opening through said deformable member remains substantially closed and a second position (when deformable member is compressed as shown in figure 7) in which said opening is opened and remains open while pressure is applied to the external member (24 & 25).

Russo also discloses that "although the present invention specifically describes opening the front connector seal via application of opposed manual force application by one hand of the operator, other manners which utilize force application on external portions of the connector which serve to open the seal are contemplated as well whether they include manual or mechanical force application or some combination of such." Therefore, Russo teaches the fingers or external member can be replaced by a mechanical device.

However, Russo lacks teaching the opening remaining open when the external member is released, as claimed in claim 1.

Iund teaches a valve assembly (400) with a slidable ring (450) that opens and closes the valve assembly by sliding a ring over a tubular member. See: figures 6 & 7. The ring (450) can be released and the valve will remain open.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have used a sliding ring (450), as taught by Iund, to apply pressure to a deformable member (24 & 25) disclosed by Russo to maintain the valve in the open position when the ring is released because of the reasonable expectation of obtaining a valve that can be rapidly opened, and remain open, without having to maintain constant manual contact with the valve assembly.

Regarding claim 2, Iund teaches an external member (ring 450) that is arranged to remain in said first (as shown in figure 7 of Iund) or second position (as shown in figure 6 of Iund) until manual force is applied to the ring to displace it to the other position.

Regarding claim 3, the ring taught by Iund is an external member that is in the form of a collar which would embrace the deformable member (via 24 & 25).

Regarding claim 4, the ring taught by Iund is an external member that is displaceable by sliding it lengthwise. See: figures 6 & 7 of Iund.

Regarding claim 5, the combined references teach a the ring of Iund which as it is slid back and forth to provide and release pressure to (24 & 25) the valve would open and close depending on the position of the ring. Thus, the valve would either be to one side of the valve or align with the valve (when ring is applying pressure).

Regarding claim 6, Russo discloses a rigid housing (22) externally of said deformable member (formed by 24,25, 29 & 30) and wherein a part of said deformable member (24 & 25) projects outwardly through an opening in said rigid housing for engagement by the external (ring) member of lund.

Regarding claim 7, Russo discloses a deformable member (formed by 24, 25, 29 & 30) that has a part with an inclined surface arranged for engagement by said external member (See figure 7 between the thumb and fingers).

Regarding claim 8, Russo discloses a housing with two openings (where 24 & 25 protrude) located opposite one another, wherein said deformable member (formed by 24, 25, 29 & 30) has two pads (24 & 25) projecting outwardly through the openings, and the two pads each have an inclined external surface (Figures 8, 10 & 11) which are shaped for engagement by the ring (450 of lund) wherein the external member (ring) when slid over the pads (24 & 25) would push inwardly towards one another thereby opening said normally closed opening. See: figures 8, 10 & 11.

Regarding claim 9, Russo discloses a normally-closed opening (28) as a slit extending diametrically of said passage. See: figures 8-12.

Regarding claim 10, Russo discloses a deformable member that is generally tubular (see figures 8-12) and has a transverse section extending across its diameter and formed integrally with said deformable member and wherein the slit (28) is provided in the transverse section. Although Russo does not specifically disclose a transverse section as a web, the transverse section of Russo provides a similar function as that claimed and using a web is a design consideration well within the skill of one having ordinary skill in the art.

Regarding claim 11, Russo discloses a substantially rigid reinforcement member (29 & 30) extending parallel to said slit (see figures 8-10) on opposite sides such that when a force is applied externally along said slit (28) said reinforcement member (29 & 30) is bowed outwardly to open said slit (see: figures 10-11).

Regarding claim 12, Russo discloses a valve with a deformable member (formed by 24, 25, 29 & 30) having a fluid passage (26) extending there through; an internal seal (figures 8-12) of a deformable material defining a slit (28) extending transversely of said fluid passage (26); and a substantially rigid reinforcement member (29 & 30) extending parallel to said slit on opposite sides such that when a force is applied externally along said slit said reinforcement member is bowed outwardly to open said slit. See: figures 8-12. Moreover, Russo teaches (column 4, lines 32-36) “Unlike the prior art duck bill valves mounted internally within the front connector (Niermann et al. US Pat. No. 5,354,267) the present invention valve 27 has thick not easily deformed sidewalls 29 and 30 of around 0.080 inches.”

Therefore, Russo teaches the valve walls as thick and not easily deformable. To any extent applicant’s reinforcement member is “substantially rigid” and yet can bow outwardly under external pressure, the reinforced thick walls that are not easily deformable would appear to comprehend the claim language.

Regarding claim 13, Russo discloses a valve with a tubular deformable member (formed by 24, 25, 29 & 30) wherein the deformable member has a fluid passage (26) extending there through, a closure member (27) extending across said fluid passage (26) and having a normally-closed slit (28) arranged such the slit can be opened by external pressure applied to said tubular member (via 24 & 25) and lund teaches an external collar (ring 450) slidable along a tubular member so that it does not apply pressure to (24 &25) in a first position in which said slit remains substantially closed and then moved to a position wherein the ring is moved to a second position (where it applies pressure to 24 &25) in which said slit is opened and remains open as long as the ring applies pressure to 24 & 25 even in the absence of any member extending within said passage.

Regarding claim 14, Russo discloses a valve with an outer rigid housing (22) having openings therein (at the ends of 22), wherein said tubular member has two projecting pads (24 &25) located at opposite sides and aligned with ends of said slit (28), and lund teaches a collar (ring) that is slidable along a housing for engagement with the pads (24 & 25) so as to apply pressure to the tubular member along the length of the slit and thereby open said slit by application of pressure.

Regarding claim 15, Russo discloses a closed system suction catheter assembly with a suction catheter (44) and a valve (27), said valve having a deformable member (formed by 24, 25, 29 & 30) and the deformable member having a fluid passage (26) extending there through, and a normally-closed opening within said passage arranged such that it can be opened by external pressure applied to said deformable member (via

24 & 25) and Iund discloses an external member (ring 450) displaceable on and separate from said deformable member. The combined references teach the deformable member as being between a first position (normally closed) at which said external member can be released and in which said opening through said deformable member remains substantially closed and a second position (when pressure is applied to 24 &25) in which said opening is opened and remains open (via sliding the ring of Iund over 24 & 25 of Russo) when said external member is released even in the absence of any member extending within said passage, the suction catheter is advancable and retractable through the passage in the deformable member (See: figures 6 & 7 of Russo, wherein the suction catheter is retracted in figure 6 and advanced in figure 7).

Regarding claim 16, Russo discloses a cleaning chamber (34) located towards a patient end of said assembly, wherein said valve (27) is located towards a patient side of said cleaning chamber and wherein said valve is operable to allow extension of said suction catheter and is closable substantially to isolate said cleaning chamber from the patient and enable cleaning of said catheter. See: figures 6-7.

Regarding claim 17, Russo discloses a valve (270 that is located towards a machine end of said assembly and is connected at a machine end of said suction catheter (44) so as to enable or prevent suctioning along said catheter.

Regarding claim 18, Russo discloses a closed system suction catheter assembly (Figures 1, 4-7) having a suction catheter (44), a machine end fitting (53) that would include a suction control valve arranged to control suction applied to a catheter, a patient end fitting (48) having a sliding seal (42) through which said suction catheter can be advanced and retracted, and a flexible envelope (31) extending between said machine end fitting and said patient end fitting and enclosing said catheter between said fittings, wherein said patient end fitting includes a cleaning chamber (34) on a patient side of said sliding seal (42), said cleaning chamber including an inlet (35) for cleaning fluid and a valve (27) , and wherein said valve includes a tubular deformable member (formed by 24, 25, 29 & 30), said deformable member having a fluid passage (26) extending there through, a closure member (27) extending across said fluid passage and having a slit (28) normally closed to isolate said cleaning chamber from the patient and lund teaches an external collar (450) slidable along a tubular member between a first position in which said slit remains substantially closed when the collar is released and a second position in which said collar applies pressure to said tubular member (via 24 & 25) to open the slit and said slit remains open when the collar is manually released to allow the catheter to be advanced from said cleaning chamber even in the absence of any member extending within said passage until the collar(ring) is manually moved to the first position.

## ***Response to Arguments***

6. Applicant's arguments filed November 10, 2008 to the have been fully considered but they are not persuasive.

7. Regarding the 35 USC 112, Second paragraph rejection, the examiner respectfully agrees that “It is well established in claim drafting that since each claim - independent and dependent-- stands on its own, it may not be accurate to say that a

valve that has the features recited in an earlier claim necessarily is "the valve" of the earlier claim. Rather, the opposite may be more accurate in that the valve of the dependent claim is "a valve" that has incorporated therein the features of the valve recited in the claim it depends from." However, in the instant case, it is unclear if applicant's "Valve" is "The valve according to Claim 1" or a different "Valve."

8. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant arguments that Russo teaches against what the examiner suggests, because the valve of Russo is only opened during a user applied force and that when the user releases the valve, it will automatically return to its closed state and that lund (which applicant has referred to as Lund) teaches a slide ring for a different purpose, namely "this is not for holding open a normally-closed opening (as in the present invention) but instead for closing a normally-open sleeve. This is used by lund in a valve for controlling the application of vacuum rather than for opening a deformable member through which a catheter is extended" have not been found convincing.

As discussed above and in the previous Office Action, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have used a sliding ring (450), as taught by lund, to apply pressure to a deformable member (24 & 25) disclosed by Russo to maintain the valve in the open position when the ring is released because of the reasonable expectation of obtaining a valve that can be rapidly opened, and remain open, without having to maintain constant manual contact with the valve assembly.

Thus, the said rejection has been maintained and made final.

### ***Conclusion***

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

10. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON OSTRUP whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771